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10/676,868	09/30/2003	Michael Slivka	DEP-5170	7650

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EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,868	SLIVKA ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12 and 14-41* is/are pending in the application.

4a) Of the above claim(s) *8-11,15 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,12,14,16-18 and 20-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of 10/27/2008 has been received and entered into the application file. Claims 5, 17, 20, 21 and 23 have been amended. Claims 1, 4-12 and 14-41 are pending in the current application, of which claims 8-11, 15 and 19 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being directed to non-elected species of the elected invention, there being no allowable generic claim. Claims 1, 4-7, 12, 14, 16-18 and 20-41 have been considered on the merits.

Response to Remarks

Applicant's remarks have been fully considered in combination with the amendments, and each will be addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn.

Double Patenting

The double patenting rejection is withdrawn because the cited co-pending application (10/676,869) has been abandoned.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Applicants have traversed the rejection under 35 USC 102(b) over Gan et al and under 35 USC 102(e) over Bilbo, on the grounds that neither Gan et al nor Bilbo have the identical disclosure that the repair material be in the form of a strip, as required by the instant claims. Applicants assert that Gan et al's description of a 'rectangular shape' is too general a description to read on a strip. Applicants assert that Bilbo's disclosure of a 'flat sheet trimmed into three or four smaller pieces' is not identical to the material being used in the present application. Applicants point to paragraph 0047 to support that the specification provides a more stringent definition of 'strip' than that cited by the Examiner.

Applicants' arguments have been fully considered, but are not found persuasive. It is respectfully submitted that Applicants are relying on limitations not in the presently examined claims. While it is noted that the cited paragraph of the specification does disclose "a substantially two-dimensionally shaped structure that is the thickness is [*sic*] at least one order of magnitude lower than either the width or length, e.g. of a thickness that will allow folding of the material in a length-wise and/or width-wide manner, *such as a strip*" (emphasis added), the specification does not define 'strip' to limit it to this particular embodiment, nor does the current independent claim recite any limitations regarding correlation between thickness and width or length or the ability to be folded. Furthermore, though Applicant has referenced Figures 3 and 4 of the instant application; however neither of Figs. 3 or 4 are of sufficient quality or detail to differentiate over the prior art. Still further, even if the figures did clearly depict a specific shape or configuration, it is still necessary for the language of the claims to define the actual invention.

With regards to Gan et al, while the disclosure of Gan et al is general, it is still considered sufficient to appropriately anticipate the current claims, as written. Figure 1 of Gan et al shows a material that has a thickness substantially less than the width and length, Gan et al disclose the material may be provided in rectangle form, a rectangle form of the material illustrated in Fig. 1 satisfies the limitation of a 'strip'.

With regards to Bilbo, it is unclear how Applicants are interpreting Bilbo such that they do not clearly disclose a strip, in any regular sense of the term? It is not necessary for the prior art disclosure to be identical to that of the current invention, but rather a rejection under 35 USC 102 is proper when the prior art disclosure *anticipates* the claimed invention. The more specific disclosure of Bilbo *anticipates* the generic term 'strip' used by the current claims.

The arguments are not found persuasive and the rejections of record stand.

Claims 1, 4, 5, 17, 18, 23, 24, 26, 27, 29 and 30 stand rejected under 35 USC 102(b) as being anticipated by Gan et al (US Patent 5,964,807).

Gan et al disclose a method for repairing spinal disc defects, comprising removing damaged tissue from the nucleus pulposus (which reads on what Applicants call preparing a disc treatment site), preparing a hybrid material of intervertebral cells and a biodegradable substrate material; and inserting the hybrid material into the intervertebral space to be repaired (See col. 5, ln 12-22). Fig. 1 shows a material having a thickness substantially less than the width and/or length. While Figure 1 shows what appears to be a circular-shaped material, Gan et al disclose the hybrid material can be provided in any shape for insertion into the intervertebral disc space of a patient, Gan et al specifically disclose a substrate having a rectangular shape (See col. 9, ln 18-30). In the absence of a more limiting definition, the word 'strip' is being given its normal definition as: "**strip (noun):** 1 a**:** a long narrow piece of a material" (Merriam-Webster Online Dictionary "Strip", URL: http://www.m-w.com/dictionary/strip accessed 5/15/08). Thus, the rectangular shaped hybrid material of Gan et al is considered to read on a 'substantially two-dimensionally shaped disc defect repair material in the form of a strip', thus insertion of such into the intervertebral disc space reads on the method of claim 1.

The biodegradable substrate material may be selected from bioactive glass, polymer foam, or polymer foam coated with sol gel bioactive materials (See col. 6, ln 30-32). Materials made from

bioactive glass or polymer foam may be porous (See col. 6, ln 53-60, col. 7, ln 27-33). The intervertebral disc cells seeded on the biodegradable substrate material may include nucleus pulposus cells (which read on what Applicants call cells obtained from spinal discs) (See col. 8, 50-61). Bioactive factors, including transforming growth factor-beta may be further provided in the biodegradable implant material (See col. 8, ln 62-col. 9, ln 5).

Therefore the reference anticipates the claimed subject matter.

Claims 1, 4-7, 17 and 26 stand rejected under 35 USC 102(e) as being anticipated by Bilbo (US 2007/0250177).

Bilbo discloses tissue engineered grafts, and methods of implanting the tissue engineered grafts to repair, augment or replace natural tissue structures in need thereof (See Pg. 2, paragraph 0010). In Example 13 Bilbo disclose repairing the annulus fibrosis (part of the intervertebral disc) by performing a discectomy (which reads on what Applicants call preparing a disc treatment site), providing a bioengineered flat sheet of ICL prosthesis (which reads on providing a disc repair material), and inserting the bioengineered flat sheet ICL into the annular hole opening (which reads on inserting the repair material into the disc to be repaired) (See Pg. 14, paragraph 0120-0124). The bioengineered flat sheet of ICL prosthesis was made of small intestinal submucosa (SIS) (See Pgs. 9-10, paragraphs 0070-0082). In the absence of a more limiting definition, the word 'strip' is being given its normal definition as: "**strip (noun):** 1 a: a long narrow piece of a material" (Merriam-Webster Online Dictionary "Strip", URL: http://www.m-w.com/dictionary/strip accessed 5/15/08). Thus, the flat sheets of ICL used by Bilbo are considered to read on a 'substantially two-dimensionally shaped disc defect repair material in the form of a strip', thus insertion of such into the intervertebral disc space reads on the method of claim 1. SIS is naturally porous, biocompatible and bioresorbable.

The ICL can further include bioactive agents, such as collagen, extracellular matrix components, growth factors, and/or seeded with cells (See Pg. 6, paragraph 0043 & Pg 8, paragraphs 0052-0056).

Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Applicants have traversed the rejection of record under 35 USC 103(a) on the grounds that primary reference Gan et al does not disclose the relative thickness of the material to the length and/or width as being suitable to permit folding and twisting.

In response, it is submitted that the rejection of record is based on the idea that the material of Gan et al maybe manipulated, as necessary, to modify the shape and size to suit the needs of the application. Therefore, even if the material of Gan et al, per se, is not of an appropriate thickness to permit folding or twisting (which is not conceded, as Applicants have provided no evidence or rationale supporting a position that the material disclosed by Gan et al cannot be folded or twisted, and the claims do not define any degree of folding or twisting which the material must be capable of enduring), it has been shown that it would have been *prima facie* obvious to modify the shape and/or size of the material such that it can be manipulated as needed.

Furthermore, while Applicants have asserted the 'relative dimensions' result in a critical ability to fold and twist, it is respectfully submitted that the claims fail to recite such specific dimensions, and there is no evidence of record to show the criticality of any such range. Therefore the arguments are considered unsubstantiated.

Therefore the arguments are not found persuasive, and the rejections of record stand.

Claims 1, 4-7, 12, 14, 16-18 and 20-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al (US Patent 5,964,807), in view of Bilbo (US 2007/0250177), Li et al (US Patent 6,764,514), Lim et al (WO 03/51239), and Moehlenbruck et al (US Patent 6,723,335).

Gan et al disclose a method for repairing spinal disc defects, comprising removing damaged tissue from the nucleus pulposus (preparing a disc treatment site), preparing a hybrid material of intervertebral cells, such as nucleus pulposus cells, and a biodegradable substrate material (providing a cell-seeded defect repair material); and inserting the hybrid material into the intervertebral space to be repaired (See col. 5, ln 12-22).

With regards to the shape of the hybrid material (defect repair material), Gan et al state the hybrid treatment material can be shaped as necessary for insertion into the defect (See Gan et al col. 9, ln 19-31); Gan et al recite a disc shape (Fig. 1), as well as a rectangular shape or a cylindrical pad. The rectangular form of Gan et al has been considered to read on the recited 'substantially two-dimensionally shaped disc defect repair material in the form of a strip' (as discussed above). However, even if the rectangular form of Gan et al is not one and the same as that currently claimed, it is submitted that modification of the defect repair material of Gan et al into a form suitable for implantation into the intervertebral disc defect, including the form of a substantially two-dimensional strip, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. One of ordinary skill in the art would have clearly optimized the shape of the repair material so as to correlate as closely as possible with the defect site to be repaired. One would have had a reasonable expectation of manipulating the shape of the repair material of Gan et al based on the fact that Gan et al clearly state the shape of the hybrid material can be manipulated, thus Gan et al shows manipulating the shape of the defect repair material was within the skill of the ordinary artisan. It has been held that differences in the shape of a material, when the shape

would be routinely optimized based on the recognized use/need, are considered to be obvious. See *In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)*. For the same reasons, it is further submitted that manipulation of the hybrid repair material of Gan et al into the form of a mushroom shape, if the defect site to be repaired has a mushroom shape, would be *prima facie* obvious.

Gan et al differs from some aspects of the instant invention in that they do not disclose using SIS as the substrate for the hybrid material. However, SIS was known as a suitable graft material for use in tissue defect repair, including for repair of intervertebral discs, see, e.g. Bilbo. Bilbo disclose bioengineered grafts comprised of ICL (derived from porcine SIS) for implantation into intervertebral disc defect sites (See Bilbo, Pg. 14, paragraphs 0120-0124). Like the hybrid materials of Gan et al, the ICL grafts of Bilbo can be seeded with cells and/or bioactive factors, including growth factors.

It has been held that substitution of a known element for another to yield predictable results would have been obvious to one of ordinary skill in the art. In the instant case, both Gan et al and Bilbo report methods for repairing damaged intervertebral discs, by removing the damage disc, and inserting a defect repair material into the defect site, each of the repair materials yield the same result: occlusion of the defect site, permitting regeneration of natural tissue. Thus, substitution of the SIS (as disclosed by Bilbo) for the substrate material of the hybrid material in Gan et al, would have been obvious to one of ordinary skill in the art.

Gan et al differs from some aspects of the instant invention in that while they disclose implanting the repair material into the disc defect, they do not specifically state the repair material is twisted or manipulated as part of the insertion step. However, it is submitted that one of ordinary skill in the art will recognize that twisting, folding, or otherwise manipulating the repair material may be necessary in order to successfully insert the material into the defect site (See, *e.g.* Li et al, as they disclose rolling, curling or

folding (all which read on twisting) an implant material to accommodate insertion into a cavity through a small opening, at col. 4, ln 40-55). Clearly if the opening made to the intervertebral disc space is smaller than the actual repair material, it would be necessary to fold, or twist the repair material in order to manipulate it through the opening into the defect site. The substrate materials disclosed by Gan et al, particularly the polymer foams, as well as SIS, if substituted as the substrate material, are recognized by the artisan as being flexible, and thus one would have a reasonable expectation that the materials could be manipulated, twisted or folded as necessary.

Gan et al differs from some aspects of the instant invention in that, while they disclose including bioactive factors, including transforming growth factor-beta, in the biodegradable implant material (See col. 8, ln 62-col. 9, ln 5), they do not specify the growth factor GDF-5. It is noted that Gan et al teach growth factors, including transforming growth factor-beta enhances cell growth (See Gan et al, col. 8, ln 62-66). A person of ordinary skill, in reading Gan et al, would have recognized the desirability of improving cell growth within the hybrid material. Lim et al teaches that GDF-5 is one of a finite number of growth factors included in the transforming growth factor-beta family, known to be useful for promoting cartilage growth (chondroinductive properties) (See Lim et al, Pg. 7, ln 9-23). Thus, it would have been obvious to a person of ordinary skill in the art to try GDF-5 as the particular transforming growth factor-beta protein provided to the hybrid material of Gan et al in an attempt to provide improved cell growth within the hybrid material of Gan et al upon implantation. It has been held that "a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." See *KSR International Co. v Teleflex, Inc.* 82 USPQ2d 1385 at 1390.

Finally, Gan et al differs from some aspects of the instant invention in that they do not disclose combining the repair material with autologous bone marrow prior to insertion into the defect site. However, at the time the invention was made, it was known in the art to be beneficial to include autologous bone marrow in intervertebral disc implant materials to increase regeneration *in situ* (See, e.g. Moehlenbruck et al, col. 5, ln 6-30); thus one of ordinary skill would have been motivated to further apply autologous bone marrow to the implant material of Gan et al, for the predictable result of increasing regeneration of the disc tissue *in situ*. One would have had a reasonable expectation of successfully providing and applying bone marrow to the implant material of Gan et al because Moehlenbruck et al disclose that use of bone marrow in intervertebral disc implants was within the purview of the artisan of ordinary skill (See Moehlenbruck et al, col. 5, ln 6-30).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/

Primary Examiner, Art Unit 1651